

FEDERAL REGISTER notice listing the additive for use;

(v) For a patent claiming a medical device, the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; the date on which the application for product approval or notice of completion of a product development protocol under section 515 of the Federal Food, Drug, and Cosmetic Act was initially submitted and the number of the application or protocol; and the date on which the application was approved or the protocol declared to be completed.

(11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined;

(13) A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (see § 1.765);

(14) The prescribed fee for receiving and acting upon the application for extension (see § 1.20(j)).

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed;

(16) A duplicate of the application papers, certified as such; and

(17) An oath or declaration as set forth in paragraph (b) of this section.

(b) Any oath or declaration submitted in compliance with paragraph (a) of this section must be signed by the owner of record of the patent or its

agent, specifically identify the papers and the patent for which an extension is sought and aver that the person signing the oath or declaration:

(1) Is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters.

(2) Has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) Believes the patent is subject to extension pursuant to § 1.710;

(4) Believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and

(5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

(c) If any application for extension of patent term submitted pursuant to this section is held to be informal, applicant may seek to have that holding reviewed by filing a petition with the required fee, as necessary, pursuant to § 1.181, § 1.182 or § 1.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 CFR 1.136.

[54 FR 9394, Mar. 24, 1987, as amended at 54 FR 30380, July 20, 1989; 56 FR 65155, Dec. 13, 1991]

§ 1.741 Filing date of application.

(a) The filing date of an application for extension of a patent term is the date on which a complete application is received in the Patent and Trademark Office or filed pursuant to the "Certificate of Mailing or Transmission" procedures of 37 CFR 1.8 or "Express Mail" provisions of 37 CFR 1.10. A complete application shall include:

(1) An identification of the approved product;

(2) An identification of each Federal statute under which regulatory review occurred;

(3) An identification of the patent for which an extension is being sought;

(4) An identification of each claim of the patent which claims the approved product or a method of using or manufacturing the approved product;

(5) Sufficient information to enable the Commissioner to determine under 35 U.S.C. 156 subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and

(6) A brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

(b) If any application submitted pursuant to this section is held to be incomplete, applicant may seek to have this holding reviewed under § 1.181.

[52 FR 9394, Mar. 24, 1987, as amended at 59 FR 54503, Oct. 22, 1993; 61 FR 64028, Dec. 3, 1996]

§ 1.750 Determination of eligibility for extension of patent term.

A determination as to whether a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for extension filed in compliance with § 1.740 or § 1.790. This determination may be delegated to appropriate Patent and Trademark Office officials and may be made at any time before the certificate of extension is issued. The Commissioner or other appropriate officials may require from applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. In an application for extension filed in compliance with § 1.740, a notice will be mailed to applicant containing the determination as to the eligibility of the patent for extension and the period of time of the extension, if any. This notice shall constitute the final determination as to the eligibility and any period of extension of

the patent. A single request for reconsideration of a final determination may be made if filed by the applicant within such time as may be set in the notice of final determination or, if no time is set, within one month from the date of the final determination. The time periods set forth herein are subject to the provisions of § 1.136.

[60 FR 25618, May 12, 1995]

§ 1.760 Interim extension of patent term under 35 U.S.C. 156(e)(2).

An applicant who has filed a formal application for extension in compliance with § 1.740 may request one or more interim extensions for periods of up to one year each pending a final determination on the application pursuant to § 1.750. Any such request should be filed at least three months prior to the expiration date of the patent. The Commissioner may issue interim extensions, without a request by the applicant, for periods of up to one year each until a final determination is made. The patent owner or agent will be notified when an interim extension is granted and notice of the extension will be published in the Official Gazette of the Patent and Trademark Office. The notice will be recorded in the official file of the patent and will be considered as part of the original patent. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be eligible.

[52 FR 9394, Mar. 24, 1987, as amended at 60 FR 25618, May 12, 1995]

§ 1.765 Duty of disclosure in patent term extension proceedings.

(a) A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of